DSJ1&2-PR Exh 591

From:	Norton, Rita on behalf of "Norton, Rita" <RNorton@amerisourcebergen.com>
Sent:	Tue, 18 Aug 2015 17:52:20 -0400 (EDT)
To:	"Zimmerman, Chris" <CZimmerman@amerisourcebergen.com>; "May, David"<DMay@amerisourcebergen.com>
Cc:	"Money, Jason R" <JMoney@amerisourcebergen.com>; "Tallamy, Brad"<BTallamy@amerisourcebergen.com>
Subject:	Fwd: Feedback requested - new proposed language on S. 483
Start Time:	Mon, 17 Aug 2015 20:00:00 -0400 (EDT)
Attachments:	Suggested Modification - Hatch Whitehouse bill section 2a2.docx;ATT00001..htm;BILLS-114s483is.pdf;ATT00002..htm

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Hi are we ok with this proposed change?

Sent from my iPhone

Begin forwarded message:

From: "Freitas, Kristen" <kfreitas@hdmanet.org>
Date: August 18, 2015 at 2:35:16 PM MDT
To: "Connie R. Woodburn (connie.woodburn@cardinalhealth.com)" <connie.woodburn@cardinalhealth.com>, "Norton, Rita" <RNorton@amerisourcebergen.com>, "pete.slone@mckesson.com" <pete.slone@mckesson.com>, "Joe Ganley (joe.ganley@mckesson.com)" <joe.ganley@mckesson.com>, "Tallamy, Brad" <BTallamy@amerisourcebergen.com>, "Money, Jason R" <JMoney@amerisourcebergen.com>
Cc: "Gallenagh, Elizabeth" <egallenagh@hdmanet.org>, "Kelly, Patrick" <pkelly@hdmanet.org>, "Carl Thorsen (Carl@Thorsen-french.com)" <Carl@Thorsen-french.com>, Alec French <Alec@Thorsen-french.com>, "Raissa Downs (rdowns@tdyllc.com)" <rdowns@tdyllc.com>, "Linda Tarplin (ltarplin@tdyllc.com)" <ltarplin@tdyllc.com>, "Jennifer Young (jyoung@tdyllc.com)" <jyoung@tdyllc.com>
Subject: Feedback requested - new proposed language on S. 483

Please keep this confidential within your company.

Staff from Senators Hatch and Whitehouse spoke with DEA and DOJ on the language changes that were suggested by Endo and Purdue Pharma. I have attached the suggested edits, as well as the introduced language in S. 483, for your reference.

DEA and DOJ expressed a concern that the suggested modification could be interpreted that DEA would be restricted to taking action only when the registrant was the one doing the diversion/improper dispensing. They would like the language to be clear that if a registrant is not the one actually diverting the controlled substance but does know of specific diversion happening down the chain, DEA would be able to take action against the registrant. They do not want to restrict their ability to use immediate suspension orders as a tool where appropriate.

Based on our conversation on what we intend to accomplish with this part of the bill, they have suggested an alternative to the definition of imminent danger in (B)(2). It would read:

> "In this subsection, the phrase 'Imminent danger to the public health or safety' means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or subchapter II of this title, there is a substantial likelihood of an immediate threat that controlled substances will be diverted for use other than legitimate medical, scientific, or industrial purposes."
>
> "Effective controls" would be the same standard found in 21 USC 823 (b), (d), (e), and (f). "Legitimate medical, scientific, or industrial purposes" is similar to the phrase "medical, scientific, or other legitimate needs" found in 21 USC 952.

Hatch and Whitehouse staff are also reaching out to Endo and Purdue Pharma to see if this addresses their concerns with S. 483.

Please let me know as soon as possible if you have concerns with this new proposed language. I will also be working with our outside counsel to get his feedback on the language.

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SECTION 2(a)(2):

(2) IMMINENT DANGER TO THE PUBLIC HEALTH OR SAFETY.—Section 304(d) of the Controlled Substances Act (21 U.S.C. 824(d)) is amended—
(A) by striking "(d) The Attorney General" and inserting "(d)(1) The Attorney General"; and
(B) by adding at the end the following:
"(2) In this subsection, the phrase 'imminent danger to the public health or safety' means that, in the absence of an immediate suspension order, controlled substances will continue to be distributed or dispensed by a registrant who knows or should know through fulfilling the obligations of the registrant under this Act, that—
"(A) ~~the~~such registrant's dispensing is outside the usual course of professional practice;
"(B) ~~the~~such registrant's distribution or dispensing poses a present or foreseeable risk of adverse health consequences or death due to the abuse or misuse of the
controlled substances; or.
"(C) as a result of such registrant's distribution or dispensing, the controlled substances will continue to be diverted outside of legitimate distribution channels.".

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II

114TH CONGRESS
1ST SESSION

S. 483

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2015

Mr. HATCH (for himself and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Ensuring Patient Access and Effective Drug Enforcement Act of 2015".

SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED SUBSTANCES ACT.

(a) DEFINITIONS.—

(1) FACTORS AS MAY BE RELEVANT TO AND CONSISTENT WITH THE PUBLIC HEALTH AND SAFE-

TY.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

"(i) In this section, the phrase 'factors as may be relevant to and consistent with the public health and safety' means factors that are relevant to and consistent with the findings contained in section 101.".

(2) IMMINENT DANGER TO THE PUBLIC HEALTH OR SAFETY.—Section 304(d) of the Controlled Substances Act (21 U.S.C. 824(d)) is amended—

(A) by striking "(d) The Attorney General" and inserting "(d)(1) The Attorney General"; and

(B) by adding at the end the following:

"(2) In this subsection, the phrase 'imminent danger to the public health or safety' means that, in the absence of an immediate suspension order, controlled substances will continue to be distributed or dispensed by a registrant who knows or should know through fulfilling the obligations of the registrant under this Act—

"(A) the dispensing is outside the usual course of professional practice;

"(B) the distribution or dispensing poses a present or foreseeable risk of adverse health con-

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sequences or death due to the abuse or misuse of the controlled substances; or

"(C) the controlled substances will continue to be diverted outside of legitimate distribution channels.".

(b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN PRIOR TO REVOCATION OR SUSPENSION.—Subsection (c) of section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended—

(1) by striking the last two sentences;

(2) by striking "(c) Before" and inserting "(c)(1) Before"; and

(3) by adding at the end the following:

"(2) An order to show cause under paragraph (1) shall—

"(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

"(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

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"(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

"(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

"(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5, United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

"(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).".

SEC. 3. REPORT TO CONGRESS ON EFFECTS OF LAW ENFORCEMENT ACTIVITIES ON PATIENT ACCESS TO MEDICATIONS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and the Director of the Centers for Dis-

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ease Control and Prevention, in coordination with the Administrator of the Drug Enforcement Administration and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, shall submit a report to the Committee on the Judiciary of the House of Representatives, the Committee on Energy and Commerce of the House of Representatives, the Committee on the Judiciary of the Senate, and the Committee on Health, Education, Labor, and Pensions of the Senate identifying—

(1) obstacles to legitimate patient access to controlled substances;

(2) issues with diversion of controlled substances; and

(3) how collaboration between Federal, State, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances.

(b) CONSULTATION.—The report under subsection (a) shall incorporate feedback and recommendations from the following:

(1) Patient groups.

(2) Pharmacies.

(3) Drug manufacturers.

(4) Common or contract carriers and warehousemen.

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(5) Hospitals, physicians, and other health care providers.

(6) State attorneys general.

(7) Federal, State, local, and tribal law enforcement agencies.

(8) Health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider.

(9) Wholesale drug distributors.

(10) Veterinarians.

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